

Remarks

This Amendment is filed contemporaneously with a Request for Continued Examination (RCE).

Claims 19-26, 28, 29, and 43-50 are pending and at issue in this application, claims 1, 2, 4, 7-16, 18, 36-39, 41, and 42 having been canceled, and claims 43-50 having been added by this amendment. Claims 3, 5, 6, 17, 27, 30-35, and 40 were previously withdrawn from the application.

Applicants respectfully traverse the rejection of claims 19-21, 24, 25, 28, and 29 as anticipated by either WO 03/103760 or Ostrowsky. In addition, applicants traverse the rejection of claims 22, 23, and 26 as obvious over WO 03/103760 or Ostrowsky. Still further, added claims 43-50 are patentable over such art for the reasons presented below.

Amended claim 19, and claims 20-23, 28, and 29 dependent thereon, specify an actuator cap including a main wall that extends generally along an axial dimension thereof and has a varying cross-sectional size. An actuator member extends transversely to the axial dimension and terminates at an outer peripheral surface wherein the outer peripheral surface extends laterally beyond a portion of the main wall but does not extend beyond a greatest lateral extent of the main wall. An upright portion that has a curved outer surface is disposed adjacent the actuator member, wherein the curved outer surface is engageable with an internal surface of a housing to guide the actuator member and prevent inadvertent actuation of the actuator member.

Claim 43, and claims 44-50 dependent thereon, recite an actuator cap including a main wall that extends generally along an axial dimension thereof and has a varying cross-sectional size. An actuator member extends transversely to the axial dimension and terminates at an outer peripheral surface wherein the outer peripheral surface extends laterally beyond a portion of the main wall but does not extend beyond a greatest lateral extent of main wall. An upright portion that has a curved outer surface is disposed adjacent the actuator member, wherein the curved outer surface prevents inadvertent actuation of the actuator member.

None of the applied art discloses or suggests an actuator cap including a main wall and an actuator member, wherein an upright portion that has a curved outer surface is disposed adjacent the actuator member, wherein the curved outer surface either prevents inadvertent actuation of the actuator member or is engageable with an internal surface of a

housing to guide the actuator cap and prevents inadvertent actuation of the actuator member as recited by claims 19-23, 28, 29, and 43-50.

In fact, WO 03/103760 discloses a medication inhaler device having a generally elongate pen shaped body housing. The housing has a delivery end 60 at a first end of a forward portion 21 that holds a nozzle assembly, a central portion 22 that acts as a casing for a medication canister 30, and a housing 23 for a cocking mechanism to actuate the medication canister 30. The housing 23 is screwed to the top of central portion 22, and the forward portion 21 is screwed to the bottom of central portion 22. The nozzle assembly includes a delivery nozzle 50, a nozzle support 52, an actuator 54, a pawl 55, and a canister support 56. The canister 30 contains medication that can be dispensed through a metered dose valve and an outlet tube 32 attached therethrough. A free end of the outlet tube 32 is inserted into the delivery nozzle 50. When medication is not being dispensed from the device, a canister leading edge rests against the canister support 56, which bears on one of two legs of the pawl 55. The two legs of pawl 55 rest on a step in a slot in the nozzle support 52. To dispense a dose of medication, a user depresses the actuator 54 protruding through forward portion 21 and a lever 40 of the cocking mechanism is rotated through approximately 90 degrees to apply pressure to the canister 30 inside the central portion 22. Depression of the actuator 54 allows the pawl 55 to slide in the direction of delivery end 60 of the inhaler by deflecting the legs of the pawl 55 away from the step within the nozzle assembly. The pressure applied by the lever 40 causes the canister 30 to move laterally toward the delivery end 60 and relative to the outlet tube 32 thereby causing the medication to be discharged into the nozzle 50 when the pawl interferes with another step within the nozzle assembly.

Ostrowsky discloses a safety actuator means including a cap 24 and a toggle-type actuator 26 that are integrally molded by injection molding. The cap 24 has a hollow body 28 with an annular bottom portion 30 that is adapted to seat on an annular rim 14 of an aerosol container 10. The exterior surface of the body 28 has two opposite sides 36 which are recessed inwardly from an arcuate circumference 34. The two opposite sides 36 are substantially parallel to each other and have a slight inward slope from the bottom portion 30 to a top 38 of the cap 24. A tab 68 of the toggle-type actuator 26 projects through each rectangular-shaped opening 40 that is disposed on both sides 36 of the cap body 28. A front side 42 of the cap body 28 is adapted receive a spout end 75 of a discharge nozzle 74 which is operatively connected to the toggle-type actuator 26. A button-type digital depressible

member 61 is operatively connected to the toggle-type actuator 26 and protrudes through an opening 48 on a top wall 45 of the cap body 28. Both tabs 68 of the toggle-type actuator 26 and the button-type digital depressible member 61 must be depressed to discharge the contents of the aerosol container 10 through the nozzle 74 disposed within the cap 24. The Ostrowsky specification states that: "Not until there is a three point pressure applied to the toggle-type actuator will the aerosol valve stem 22 operate to an open position. This makes it virtually impossible for a child to operate the aerosol unit and provides the safety factor." (Col. 4, lines 51-55).

Contrary to the examiner's assertion, neither WO 03/103760 nor Ostrowsky discloses "an upright portion having a curved outer surface disposed adjacent the actuator member ..." as recited by the claims at issue. In fact, the part denoted by reference number 50 in FIG. 3 of WO 03/103760 refers to a delivery nozzle that does not engage anything. Similarly, the part denoted by reference number 74 in FIG. 7 of Ostrowsky refers to a discharge nozzle that also does not engage any structure (*See* Col. 4, lines 1-4). Because the applied references do not disclose or suggest each of the elements recited by the claims at issue, it follows that such claims are not anticipated thereby.

Although the Supreme Court has held that the "teaching, suggestion, motivation" test should not be strictly applied, *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), the Court also noted that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* Instead, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.* There is no apparent reason that would prompt a person of ordinary skill in the relevant field to modify the elements of WO 03/103760 and/or Ostrowsky in the manner as recited by the claims at issue. Specifically, the subject matter recited in the claims at issue is not rendered obvious by either Ostrowsky or WO 03/103760, because the applied art does not even suggest an incentive for a person of ordinary skill in the art to provide the missing elements thereof in order to arrive at the claimed subject matter.


Further, because the dependent claims at issue incorporate the subject matter of the respective independent claims, it follows that the dependent claims are also allowable for the reasons presented above. Therefore, reconsideration and withdrawal of the rejections of the claims and allowance thereof are respectfully requested.

Deposit Account Authorization

The Commissioner is hereby authorized to charge any deficiency in any amount enclosed or any additional fees which may be required during the pendency of this application under 37 CFR 1.16 or 1.17, except issue fees, to Deposit Account No. 50-1903.

Respectfully submitted,

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July 13, 2007

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